DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

Re: VIBATIV
Patent Nos. 6,635,618; 6,872,701;
and 7,208,471
Docket Nos.: FDA-2010-E-0022
FDA-2010-E-0023
FDA-2010-E-0024

OCT 28 2010

The Honorable David J. Kappos
Undersecretary of Commerce for Intellectual Property
Director of the United States Patent and Trademark Office
Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Kappos:

This is in regard to the applications for patent term extension for U.S. Patent Nos. 6,635,618; 6,872,701; and 7,208,471, filed by Theravance, Inc., under 35 U.S.C. section 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for VIBATIV (televancin hydrochloride), the human drug product claimed by the patent.

The total length of the regulatory review period for VIBATIV (televancin hydrochloride) is 2,635 days. Of this time, 1,637 days occurred during the testing phase and 998 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: June 27, 2002.

   FDA has verified the applicant's claim that the date the investigational new drug application became effective was on June 27, 2002.

2. The date the application was initially submitted with respect to the human drug product under section 505 of the Federal Food, Drug, and Cosmetic Act: December 19, 2006.

   The applicant claims December 7, 2006, as the date the new drug application (NDA) for VIBATIV (NDA 22-110) was initially submitted. However, FDA records indicate that NDA 22-110 was submitted on December 19, 2006.

3. The date the application was approved: September 11, 2009.

   FDA has verified the applicant's claim that NDA 22-110 was approved on September 11, 2009.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. section 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: Jeffrey A. Hagenah
Theravance, Inc.
Patent Department
901 Gateway Blvd.
South San Francisco, CA 94080